DETAILED ACTION

Status of Claims

Claims 1-11, 13, 15, 17 and 19 are pending in this application. Claims 12, 14, 16 and 18 have been cancelled. This action is in response to the applicants' filing of a notice of appeal on September 15, 2009. A typographical error in the previous action misinformed applicants that the action was final. Their response was improper as the previous action was not a final action, however it will be treated as a response to a non-final action and the arguments will be addressed accordingly.

Withdrawn Rejections/Objections

Applicant is notified that any outstanding rejection/objection that is not expressly maintained in this office action has been withdrawn or rendered moot in view of applicant's amendments and/or remarks.

Claim Rejections - 35 USC § 112, 1st paragraph

Claims and 17 and 19 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of treating depression does not reasonably provide enablement for any other diseases or disorders stated within the claims. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Applicants have stated that inoperative embodiments are interpreted to be *per se* functional. Here the applicants put forth an argument as to whether non-operative embodiments present in the claim would result in undue experimentation for one of

ordinary skill in the art. Applicants discussed in the specification how bioavailability was determined. However examiners arguments do not revolve around the bioavailability of the compounds.

The arguments presented by the applicants do not seem to be on point. Applicants have focused their arguments on the bioavailability of the compounds and how they possess a greater bioavailability than previous similar compounds. Examiner has not made mention nor argued whether the compounds have better bioavailability. The fact that the compounds can cause a higher level of serotonin in the brain of a rat does not provide guidance how to treat specific diseases and or disorders.

The claims are to be interpreted in their broadest reasonable interpretation. Examiner need only look at the list of diseases that applicants claim are “treatable” to determine that several diseases are not enabled. For example, certain types of brain or spinal cord trauma are untreatable. One would not envision a spinal cord-related paralysis to be treatable by an increase in serotonin levels. Likewise several different types of eating disorders exist. Several of these eating disorders arise from reasons that are not biological, such as cultural or family pressures, which means no amount of serotonin increase will treat this disease. (http://www.umm.edu/patiented/articles/what_causes_eating_disorders_000049_3.htm, last accessed February 16, 2010), likewise there are a variety of different sexual dysfunctions. While some are biological, some are not. In addition, some of those which are biological are not treatable. The following website: http://www.wrongdiagnosis.com/s/sexual_dysfunction/causes.htm

lists a variety of causes of sexual dysfunctions. As can be seen, male infertility is one of the diseases covered under "sexual dysfunction". Male infertility is not presently treatable by an increase in serotonin levels.

Second, applicants claim that they did not provide several documents in the previous action to show the "state of the art" but rather to show the "voracity of the claims in the specification that treatment of the various indications clamed is enabled." The previous response states, "…accordingly it is submitted that these references provide evidence that the presently claimed compounds which are serotonin reuptake inhibitors have utility in the methods stated in the claims." Examiner would like to clarify that the utility of the application is not in question, only the enablement. Applicants do not discuss the diseases and disorders in any detail. All that is stated is a correlation that if these compounds can increase serotonin levels then they must also be suitable for the treatment of several diseases. No testing (*in vivo* or other) is seen or discussed relating directly to any of the mentioned diseases. Applicants provided in the last response a list of papers, patents, documents, etc that show a correlation between various diseases and serotonin reuptake inhibition. Thus, these non-patent literature documents are, as applicants have suggested, capable of showing only that there is a utility, but cannot provide any type of enablement support at the time *the current application was filed.* Therefore, these documents cannot be used in an argument rebutting the scope of enablement of the diseases as they cannot describe the state of the art when the application was filed. The examiner has stated that "a method for

treating depression" is enabled. No new matter permitted. Appropriate correction is required.

Allowable Subject Matter

Claims 1-11, 13 and 15 are allowed.

Claims 1-11, 13 and 15 are free of the prior art. No prior art is seen which contains compounds of Formula I in the current application's claim 1.

Conclusion

Claims 1-11, 13 and 15 are allowed.

Claims 17 and 19 are rejected.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey H. Murray whose telephone number is 571-272-9023. The examiner can normally be reached on Mon.-Thurs. 7:30-6pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisors, James O. Wilson can be reached at 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jeffrey H Murray/
Patent Examiner , Art Unit 1624